UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,272	07/17/2003	Shanta M. Modak	070050.2429	4202

21003 7590 12/21/2009

BAKER BOTTS L.L.P.
30 ROCKEFELLER PLAZA
44TH FLOOR
NEW YORK, NY 10112-4498

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
12/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary	Application No.	Applicant(s)	
	10/622,272	MODAK ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13,15,17 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-13, 15, 17, and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 9/29/2009, are acknowledged and entered. Claims 1-9, 11-13, 15, 17, and 31-34 are pending and under examination.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2009 has been entered.

Response to Arguments

Applicants' arguments, filed 9/29/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 9/29/2009. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Objections

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 depends from claim 1. Claim 1 recites an anti-irritant composition comprising (b) one *or more* antimicrobial compounds selected from the group

consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, *and combinations* thereof at a concentration of between 0.05%-4% (weight/weight). Claim 11 recites that "the antimicrobial compound" is selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, *phenoxyethanol, polymyxin B, neomycin, triclosan, parachlorometaxylene, octoxyglycerin*, and combinations thereof. Claim 11 expands, rather than further limits, the selection of antimicrobial agents recited in claim 1.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-13, 15, 17, and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 33 recite an anti-irritant composition comprising (b) one *or more* antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, *and combinations* thereof at a concentration of between 0.05%-4% (weight/weight). When two or more of the recited antimicrobial compounds are present in combination, it is unclear from the specification and claims whether the claimed concentration of 0.05%-4% (weight/weight) refers to the concentration of the individual antimicrobial agents or the combined amount of the antimicrobial agents.

Claim Rejections - 35 USC § 112 – 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-13, 15, 17, and 31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to an anti-irritant composition comprising:

(a) two or more water-soluble, organic salts of zinc, wherein said water-soluble, organic salts of zinc are present in said anti-irritant composition at concentrations between 0.1% and 2% (weight/weight),

(b) one or more antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbuty1 carbamate, and combinations thereof at a concentration of between 0.05% - 4% (weight/weight),

(c) 0.05% - 4% (weight/weight) incroquat,

(d) water,

(e) 60% - 95% ethanol, and

(f) one or more agent selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient, wherein the composition exhibits a synergistic preservative effect against bacteria (claims 1-9, 11-13, 15, 31-32, and 34);

or an anti-irritant composition comprising:

(a) two or more water-soluble, organic salts of zinc, wherein said water-soluble, organic salts of zinc are present in said anti-irritant composition at concentrations between 0.1% and 2% (weight/weight),

(b) one or more antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, and combinations thereof at a concentration of between 0.05% - 4% (weight/weight),

(c) 0.05% - 4% (weight/weight) incroquat,

(d) water,

(e) 60% - 95% ethanol, and

(f) one or more agent selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient, and further wherein the composition does not comprise zinc salicylate, wherein the composition exhibits a synergistic preservative effect against bacteria (claim 33).

The disclose lacks written description of specific compositions that exhibit a "synergistic preservative effect against bacteria" as recited in the instant claims.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claims indicates that these claims are drawn to generic anti-irritant compositions purported to have a synergistic preservative effect against bacteria.

To provide adequate written description and evidence of possession of such compositions, the specification must provide sufficient distinguishing characteristics of the compositions. In the instant case, the specification discloses gel compositions comprising water, "U care", ethanol, glycerin, cetylether, chlorhexidine gluconate, benzalkonium chloride, and incroquat (Table 10) and the effect of these gels on the growth of *S. aureus* bacteria. All of these gels contained specific amounts of water (32.25 to 33.3 weight percent), U Care (0.2 weight percent), ethanol (65 weight percent), glycerin (1.0 weight percent), cetylether (0.5 weight percent), chlorhexidine gluconate (0.05 weight percent), benzalkonium chloride (0.125 weight percent), and incroquat (0.3 or 0.6 weight percent). Gel #6 further contained 0.15% zinc gluconate, 0.1% zinc acetate, and 0.05% zinc lactate. While these specific gel compositions exhibited a synergistic preservative effect against *S. aureus* bacteria, there is no disclosure of other compositions having a synergistic preservative effect against *S. aureus* bacteria or other types of bacteria as broadly encompassed by the claims.

The instant claims encompass embodiments comprising only one antimicrobial compound in an amount ranging from 0.05% to 4%. Applicants have not described any compositions comprising, for example, 0.1% zinc salicylate, 0.1% zinc tartrate, 0.05%

iodopropynylbutyl carbamate, 0.05% incroquat, water, and 95% ethanol having a synergistic preservative effect against bacteria.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed compositions, which are generic compositions, purported to exhibit a synergistic preservative effect against bacteria. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the broadly claimed compositions having such synergistic preservative effect against bacteria. Requiring the skilled artisan to carry out random hit-or-miss testing to determine which compositions, out of all compositions comprising:

(a) two or more water-soluble, organic salts of zinc, wherein said water-soluble, organic salts of zinc are present in said anti-irritant composition at concentrations between 0.1% and 2% (weight/weight),

(b) one or more antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbuty1 carbamate, and combinations thereof at a concentration of between 0.05% - 4% (weight/weight),

(c) 0.05% - 4% (weight/weight) incroquat,

(d) water,

(e) 60% - 95% ethanol, and

(f) one or more agent selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient, actually have a synergistic preservative effect against bacteria as recited in the instant claims is *prima facie* evidence that Applicants were not in possession of the broadly claimed compositions having a synergistic preservative effect against bacteria. The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-13, 15, 17, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Modak *et al.*** (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) and **Modak *et al.*** (U.S. Patent No. 5,965,610; Issued Oct. 12, 1999; Filed Jun. 9, 1997) in view of **Wei *et al.*** (U.S. 2002/0098159 A1; Published Jul. 25, 2002; Filed May 18, 2001).

The instant claims recite compositions comprising:

(a) two or more water-soluble, organic salts of zinc, wherein said water-soluble, organic salts of zinc are present in said anti-irritant composition at concentrations between 0.1% and 2% (weight/weight),

(b) one or more antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbuty1 carbamate, and combinations thereof at a concentration of between 0.05% - 4% (weight/weight),

(c) 0.05% - 4% (weight/weight) incroquat,

(d) water,

(e) 60% - 95% ethanol, and

(f) one or more agents selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient, wherein

the composition exhibits a synergistic preservative effect against bacteria. Claim 33 recites the same composition of claim 1, wherein the composition does not comprise zinc salicylate.

Modak *et al.* ('918) teach of the use of organic salts of zinc in anti-irritant topical formulations (Abstract).

Organic salts of zinc include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laurate, zinc stearate, zinc lactate and zinc propionate (col. 1, lines 56-60) as recited in instant claims 2 and 34.

The organic salts of zinc may be comprised in a cream base, which may be hydrophilic or hydrophobic (col. 2, lines 8-9). Said cream bases are known to include water, dimethicone, glycerin and other excipients such as vitamin E as recited in claims 5 and 31 (*id.* at lines 10-26). Examples of such lotions include "Soft-Sense" which is known to contain water, glycerin, distearyldimonium chloride, petrolatum, isopropyl palmitate, 1-hexadecanol, Vitamin E, dimethicone, titanium dioxide, methyl paraben, propyl paraben, sodium chloride, and fragrance and "Curel" which is known to contain water, glycerin, quaternium-5, petrolatum, isopropyl palmitate, 1-hexadecanol, dimethicone, sodium chloride, fragrance, methyl paraben,and propyl paraben (col. 2, lines 16-26)

The concentration of organic salts of zinc may vary from between 1 to 15% and in a particular embodiment, may comprise 0.1 to 1% zinc salicylate (*id.* at lines 27-30 and lines 36-45)). This suggests and motivates the amounts of zinc salts as recited in claim 1.

Further, in addition to zinc salicylate, the compositions may comprise "one or more other organic salts of zinc", thus motivating the inclusion of "two or more" zinc salts as recited in instant claim 1 (*id.* at lines 30-31). Examples of such compositions comprising two or more zinc salts are provided in Tables A and B.

With respect to the amounts of water and emollients recited in the instant claims, if the compositions taught in Modak *et al.* comprise about 1 to 15% organic zinc salt in a cream base, the remaining percentage must be comprised of water and emollients. Modak *et al.* do not teach compositions further comprising incroquat or an antimicrobial compound.

However, Modak *et al.* ('610) teaches zinc gluconate gel-containing topical compositions which have an anti-irritant effect on the skin (Abstract). Said topical compositions further comprise chlorhexidine gluconate (*id.*). Chlorhexidine gluconate is an antimicrobial agent

recited in instant claims 1 and 33. The compositions of Modak *et al.* can contain anti-microbial agents or combinations of anti-microbial agents (col. 4, lines 57-59) such as benzalkonium chloride and chlorhexidine and salts thereof as recited in the instant claims (col. 5, lines 2-3 and 15-40). In fact, Modak et al. explicitly teach that "anti-microbial synergist" is used to refer to substances which in combination with an antimicrobial agent produce a microbiocidal effect greater than the added microbiocidal effects of the substance and the antimicrobial agent used separately. In this regard, Modak et al. teach antimicrobial synergists for use in the invention when the antimicrobial agent is chlorhexidine of salt thereof include benzalkonium chloride as recited in the instant claims (col. 9, lines 13-30).

The gels of the topical compositions may be formed from 1-10 percent zinc gluconate, 0.4-4 percent chlorhexidine gluconate and 2 to 20 percent purified water (col. 26, lines 14-18). Such amounts obviate the amounts of zinc salts, antimicrobial agent, and water as recited in claims 1, 3, and 33.

The compositions of Modak et al. ('610) may be added to preexisting formulations such as creams and lotions that are commercially available. Examples of such lotions include "Soft-Sense" which is known to contain water, glycerin, distearyldimonium chloride, petrolatum, isopropyl palmitate, 1-hexadecanol, Vitamin E, dimethicone, titanium dioxide, methyl paraben, propyl paraben, sodium chloride, and fragrance and "Curel" which is known to contain water, glycerin, quaternium-5, petrolatum, isopropyl palmitate, 1-hexadecanol, dimethicone, sodium chloride, fragrance, methyl paraben,and propyl paraben (col. 10, lines 40-60).

Creams for use as topical compositions may comprise a water phase comprising 0.05-4 percent Ucare JR-400, which is an emollient as recited in claim 4 and which contains a "polyquaternium compound" as recited in claim 5, 0.5-5 percent crodamol, which is a gelling or thickening agent as recited in claims 6 and 7, and 1-10 percent incroquat behenyl TMS, which is "incroquat" as recited in claims 1 and 33 (col. 26, lines 18-26).

The primary and secondary references thus teach, suggest, and motivate topical compositions comprising two or more zinc salts (*e.g.*, zinc gluconate and zinc salicylate), one or more antimicrobial compounds (*e.g.*, benzalkonium chloride and chlorhexidine gluconate), and further comprising water, ethanol, and one or more agents selected from the group consisting of

gelling agents and/or thickening agents (*e.g.*, crodamol), hydrophilic or hydrophobic polymers (*e.g.*, dimethicone), emulsifying agents, and emollients (*e.g*, UCare JR-400 and/or glycerin).

Wei *et al.* discloses that benzalkonium chloride is a known non-cationic antimicrobial agent (page 7, [0096-0098]) and that the oils recited in claim 32 and are known naturally occurring antimicrobial agents (pages 9-10, [0256]). Wei *et al.* further teach that the claimed gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients are known excipients useful in topical cream compositions. In this regard, Wei *et al.* disclose mildness enhancers including cationic and nonionic polymers, co-surfactants, moisturizers, and mixtures thereof such as polyethylene and polypropylene glycols and silicone polymers in amounts ranging from 0.1 to 1% (page 10, [0260]). Silicone oils such as mixtures of dimethicone and dimethiconol are disclosed at page 10, [0267] and non-volatile silicones ranging from 0.01 to 5% as degreasing agents are disclosed at page 12, [0283]. Stabilizers comprising a polymeric thickener such as hydroxy ethyl cellulose or polyquaternium 10 in amounts ranging from 0.01 to 5% are disclosed at page 13, [0305].

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have formulated a topical composition comprising the claimed excipients. Modak *et al.* ('918) suggest the use of two or more organic zinc salts as anti-irritant components of topical compositions. While Modak *et al.* ('918) do not teach the addition of antimicrobial agents to said topical compositions, Modak *et al.* ('610) teach topical compositions containing zinc gluconate and one or more antimicrobial agents such as chlorhexidine gluconate also have an anti-irritant effect on the skin. Modak *et al.* ('610) further suggest that mixtures of antimicrobial agents can be used in the compositions disclosed therein.

One of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that addition of one or more anti-microbial agents to the topical compositions disclosed in Modak et al. ('918) would result in a topical composition having anti-microbial activity with minimal irritation based on the combined teachings of the cited references. With respect to the recited gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients, such excipients are well established in the art as useful in the formulation of topical compositions as taught by Modak *et al.* ('918), Modak *et al.* ('610), and Wei *et al.* As such, it is well within the purview of the skilled artisan

using no more than routine experimentation to combine these agents in suitable amounts in a topical composition.

The implicit motivation to combine to the cited references is based on the fact that Modak *et al.* and Modak *et al.* are both drawn to compositions comprising zinc salts for use as anti-irritant topical compositions, optionally containing one or more anti-microbial agents (Modak *et al.* ('610)). Wei *et al.* is also drawn to topical compositions containing anti-microbial agents. As such, one skilled in the art could readily envision formulation of a topical composition containing two or more zinc salts as suggested and motivated by Modak *et al.* ('918) and further containing one or more anti-microbial agents as suggested and motivated by both Modak *et al.* ('610) and Wei et al. The skilled artisan would expect that two anti-microbial agents would be more effective than only one anti-microbial agent in such compositions.

Response to Arguments

Applicants traverse the instant rejection, stating that the claims as amended are not obvious over the cited references when considered separately or in combination. Applicants submit that the presently claimed invention is directed to two or more water-insoluble, organic salts of zinc present in an anti-irritant composition at concentrations between 0.1% and 2% (weight/weight), an antimicrobial compound selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, at a concentration of between 0.05% - 4% (weight/weight), 0.05% to 4% (weight/weight) incroquat, water, 60%-95% ethanol, and one or more agents selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient, wherein the composition exhibits a synergistic preservative effect against bacteria. Applicants argue that the claimed invention is not obvious over the cited references because the combined teachings of the '918 patent, the '610 patent, and Wei fail to disclose all of the elements of the claimed invention and also that the claimed invention is directed to a composition having unexpected results. Specifically, Applicants submit that the combination of incroquat with chlorhexidine gluconate and benzalkonium chloride unexpectedly and significantly potentiates the preservative effects of the composition.

Firstly, Applicants submit that the teachings in the '918 patent are limited to compositions that combine zinc salts to reduce irritations by a host of irritants. More specifically, Applicants allege that the '918 patent requires that any composition comprising two or more organic salts of zinc to include zinc salicylate as at least one of the species, referring to column 2, lines 27-67. This argument is not persuasive because while the '918 patent exemplifies compositions comprising zinc salicylate, nowhere do the inventors of the '918 patent teach that the compositions disclosed therein *require* zinc salicylate be one of the zinc salts in the composition. See especially column 1, lines 53-55, "The present invention relates to compositions and methods whereby organic salts of zinc are used in anti-irritant creams for topical application" and column 1, lines 56-60, "Organic salts of zinc *which may be used according to the invention* include, but are not limited to, zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laureate, zinc stearate, zinc caproate, zinc gallate, zinc lactate, zinc myristate, zinc palmitate, and zinc propionate". Furthermore, the '610 patent suggests and motivates topical anti-irritant compositions comprising zinc gluconate and anti-microbial agents or combinations of anti-microbial agents such as benzalkonium chloride and chlorhexidine. As such, combining two more zinc salts with antimicrobial agents in a topical anti-irritant composition would have been obvious to one of ordinary skill in the art at the time the invention was made.

Secondly, Applicants argue that the '610 patent merely discloses that zinc salts can prevent multiple irritant-inactivating substances from binding to a surface and that the patent discloses that in attempting to form a gel-matrix with an antimicrobial agent, zinc gluconate was the only "metal salt" that could be formulated with the antimicrobial to successfully produce the gel-matrix. Applicants thus assert that because different zinc salts can exhibit different properties with regard to combination formulations, an artisan of ordinary skill would not have predicted that any zinc salt, let alone two or more zinc salts, could be successfully combined in a single composition with specific antimicrobial agents and incroquat, as recited in the instant claims. This argument is not deemed to be persuasive because as a first matter, the instant claims do not require that the composition is in the form of a gel as recited in the '610 patent. As such, even if zinc salts other than zinc gluconate do not form a gel matrix, this is not pertinent to the present rejection. Furthermore, there is nothing in the '610 that suggests that *addition* of

another zinc salt to a zinc gluconate containing gel will destroy the gel-matrix formed by the presence of zinc gluconate. Both the '918 and '610 patents teach, suggest, and motivate topical compositions comprising one or more zinc salts as recited in the instant claims, optionally in combination with one or more antimicrobial agents. As such, there is nothing unobvious about combining two or more zinc salts and one or more antimicrobial agents in a topical composition as recited in the instant claims.

Thirdly, Applicants argue that the '610 and '918 patents would not have provided a basis for the skilled artisan to predict that the low zinc salt concentrations of the presently claimed invention as combined with specific antimicrobials and incroquat would have a synergistic effect, and as such the claims are not obvious over the cited references. Regarding the alleged unexpected results, Applicants argue that compositions of the invention have a surprising and unexpected synergistic antimicrobial effect. In support of this argument, Applicants point to Example 10 of the application (pages 47-52) wherein the combination of chlorhexidine gluconate, benzalkonium chloride, and incroquat in a single composition resulted in an antimicrobial effect that was greater than the expected additive effect of the three compounds. Table 10, which shows the compositions tested in Example 10 is reproduced below for ease of discussion.

Table 10. Compositions of Gels Containing Various Combinations of Chlorhexidine Gluconate and Benzalkonium Chloride and Incroquat.

Ingredients	Gel # 1	Gel #2	Gel #3	Gel #4	Gel #5	Gel #6
Water	33.3	33.125	33.0	32.825	32.525	32.25
U care (JR30)	0.2	0.2	0.2	0.2	0.2	0.2
Ethanol	65	65	65	65	65	65
Glycerin	1.0	1.0	1.0	1.0	1.0	1.0
Cetylether PPG10)	0.5	0.5	0.5	0.5	0.5	0.5
CHG	-	0.05	-	0.05	0.05	0.05
BZK	-	0.125	-	0.125	0.125	0.125
Incroquat	-	-	0.3	0.3	0.6	0.6
Zinc gluconate	-	-	-	-	-	0.15
Zinc acetate	-	-	-	-	-	0.1
Zinc lactate	-	-	-	-	-	0.05

Firstly, it is noted that there is only one composition (Gel #6) that is within the scope of the instantly claimed compositions, i.e., that contains two or more zinc salts. Secondly, the synergistic antimicrobial activity demonstrated with the compositions of Example 10 is limited to antimicrobial activity against a single bacteria type, *S. aureus*. Lastly, the compositions for which a synergistic antimicrobial activity against *S. aureus* is demonstrated are not commensurate in scope with the patent protection sought in the instant claims. For example, the compositions in Table 10 contain a specific combination of chlorhexidine gluconate, benzalkonium chloride, and incroquat in particular amounts, whereas the instant claims encompass compositions comprising "one or more antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, and combinations thereof". Applicants have demonstrated no unexpected synergistic antimicrobial activity for a composition comprising, for example, only benzalkonium chloride and incroquat as encompassed by the instant claims. The compositions in Table 10 additionally comprise specific zinc salts, *i.e.*, zinc gluconate, zinc acetate, and zinc lactate, whereas the instant claims encompass compositions comprising "two or more water-soluble, organic salts of zinc". Lastly, the amounts of chlorhexidine gluconate, benzalkonium chloride, and incroquat in the compositions of Table 10 are not commensurate in scope with the amounts of these agents encompassed by the instant claims. Applicants have presented no factual evidence that the synergistic activity observed against *S. aureus* when 0.05% chlorhexidine gluconate, 0.125% benzalkonium chloride, and 0.3% or 0.6% incroquat are combined is also observed when 4% chlorhexidine gluconate, 2.5% benzalkonium chloride, and 3% incroquat are combined as encompassed by the instant claims.

Accordingly, the Examiner is not persuaded that Applicants have demonstrated unexpected results that are commensurate in scope with the claimed compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614